

Appl. No. : 10/085,169
Filed : February 25, 2002

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REMARKS

In response to the Office Action mailed July 5, 2006, Applicants respectfully request the Examiner to reconsider the above-captioned application in view of the foregoing amendments and the following comments. As a result of the amendments listed above, Claims 1-3, 5-8, 11 and 12 remain pending. Claims 1 and 5 have been amended.

In the changes made by the current amendment, ~~deletions are shown by strikethrough~~, and additions are underlined.

The Examiner Is Performing A Hindsight Reconstruction

It is the Applicants position that the Examiner has impermissibly used Applicant's Claims as blueprints to search piecemeal through the prior art to attempt to reconstruct the subject matter of Applicant's Claims. The U.S. Court of Appeals for the Federal Circuit has repeatedly rejected such attempts to use hindsight to show the obviousness of a patent Claim. *In re Gorman*, 933 F.2d 982 (Fed. Cir. 1991) ("As in all determinations under 35 U.S.C. section 103, the decisionmaker must bring judgment to bear. It is impermissible, however, simply to engage in a hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps.").

As is discussed in greater detail below, the combinations proposed by the Examiner are improper at least due to a lack of suggestion or motivation to combine originating in the prior art. Many of the combinations proposed by the Examiner have been made in direct response to Applicants arguments regarding the inadequacy of individual prior art references and the proposed combinations of these references. The number of references has continually increased in over the course of the examination of the present application as the Examiner has used the Applicants' invention as a blueprint to locate and combine individual prior art references to reconstruct the claimed invention. Applicants submit that such a hindsight reconstruction is improper and request reconsideration and allowance of Claims 1-3, 5-8, 11 and 12.

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The Lampropoulos et al. and Abiuso et al. Combination Is Improper

Claims 1-3,5-8,11, and 12 currently stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lampropoulos et al. in view of Abiuso et al., Loffler, and Saab; and Lampropoulos et al. in view of Abiuso et al., Loffler, Saab, and Stevens. The Examiner has taken the position that Abiuso et al. teaches that holes and slits are functional equivalents and when applied to the catheter of Lampropoulos et al. will result in the claimed invention with the exception of the claimed relationship between the lumen cross-sectional area and the combined exit hole area, which is later addressed with the use of the Loeffler and Saab references.

Contrary to the assertion of the Examiner, the Abiuso et al. reference does not teach that slits and holes are functional equivalents. Applicants do submit that the paragraph cited by the Examiner (Column 5 lines. 25-29) discloses that, as used in the Abiuso et al. reference, the term holes can also mean slits. However, in the next paragraph Abiuso et al. continues to explain how an "advantage" of the slits, as opposed to the holes, is that the fluid will not bleed out until a minimum pressure is applied. This is a clear understanding by Abiuso et al. that the holes and slits function differently and produce different characteristics of the balloon system. Simply because Abiuso et al. has stated that the some embodiments can utilize holes, while other embodiments utilize slits, it does not necessarily follow that holes and slits are functional equivalents. Therefore, not only does the prior art relied upon by the Examiner not teach that the holes and slits are functional equivalents; it clearly discloses that holes and slits are not functional equivalents and thus explained the functional differences accordingly.

For at least these reasons Applicants respectfully submit that the combination of Lampropoulos et al. and Abiuso et al. is improper, at least for the teaching or suggestion argued by the Examiner, and request reconsideration and allowance of Claims 1-3, 5-8, 11 and 12

The Loeffler and Saab Combination Is Improper

The Examiner has taken the position that it would have been obvious to combine the disclosure that the profusion ports of Loeffler could be varied in size with the disclosure that the lumen of Saab could be varied in size to arrive at the claimed catheter in which, among other limitations, the combined area of the exit holes is less than the cross-sectional area of the lumen. Applicants respectfully disagree.

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In regard to the Loeffler reference, a catheter is disclosed that includes some perfusion ports (1, 2) that are spaced from one another on the side wall of the catheter. The reference further discloses that the size and shape of the ports may be altered as needed, presumably to achieve a desired flow rate through the catheter. However, because the reference is primarily directed toward a stent delivery system, no guidance as to the desired size of the ports, or flow rate through the catheter, is provided. Loeffler makes no reference to the importance or challenge of attaining uniform fluid flow over all of the perfusion ports.

Further, and perhaps most importantly, Loeffler makes no disclosure regarding a relationship between the combined area of the perfusion ports and the cross-sectional area of the lumen. Applicants submit that the disclosure of altering the perfusion ports as needed or desired does not teach or suggest anything regarding the claimed relationship between the aggregate area of the exit holes and the minimum cross-sectional area of the lumen.

In regard to the Saab reference, Applicants submit that the reference does disclose that altering the cross-sectional area of the lumen of the heat transfer catheter will change the flow rates through, and the pressure gradients within, the lumen of the catheter. The reference does not, however, disclose information that connects this flow rate inside the lumen to the rate, or evenness of distribution, of any fluid flowing out of the lumen and into an anatomical region. Furthermore, the catheter of the Saab reference is a heat transfer catheter in which the fluid flowing within the catheter lumen does not exit the lumen of the catheter. Thus, the Saab reference does not suggest anything to one of skill in the art regarding the claimed relationship between the aggregate area of the exit holes and the minimum cross-sectional area of the lumen.

As discussed at length above, and in the prior amendments, the claimed catheter includes, among other recitations, a specific relationship between the cross-sectional area of a catheter lumen and the combined area of all of the exit holes of the catheter. The Loeffler and Saab references, on the other hand, consider the exit hole size parameter and the catheter lumen size parameter independently. Loeffler discloses altering exit hole size, but does not discuss altering the flow rate through the lumen. Saab discloses altering lumen cross-sectional area, but does not deliver the fluid from the catheter. The fluid merely re-circulates within the catheter. As a result, there is no suggestion or motivation within the prior art to combine these references at all, much

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less to combine the references and arrive at the claimed invention. For at least this reason, the applied combination of Loeffler and Saab is improper.

Teachings Of The Prior Art Do Not Support The Optimization Argument Proposed By The Examiner

In response to the Examiner's position that the specifically-claimed relationship between the combined area of the exit holes and the cross-sectional area of the lumen would be a result of routine experimentation, Applicants submit that this conclusion is irrelevant because the combination of Lampropoulos et al. in view of Abiuso et al., Loffler, and Saab and the combination of Lampropoulos et al. in view of Abiuso et al., Loffler, Saab, and Stevens are improper. For the sake of argument, even if the combination were proper, the Loeffler and Saab references only disclose that altering the individual dimensions may alter some respectively individual operating parameters.

As discussed above, the Loeffler reference only teaches that the holes sizes of a catheter may be altered individually. Accordingly, this reference may provide an appropriate the basis for a case of optimization of a range for a hypothetical invention regarding a catheter having specifically-sized exit holes. However, Applicants submit that the presently claimed invention does not deal with the optimization of the exit hole size, but is directed toward the critical relationship between the aggregate area of the exit holes and the cross-sectional area of the lumen.

Similarly, the Saab reference only discloses that one may alter the size of a lumen of a catheter. Thus, the reference only discloses variation of a single parameter and makes no explicit disclosure, or even a suggestion, of the critical relationship between the cross-sectional area of a lumen and the combined area of the exit holes. As with the Loeffler reference, the Saab reference may provide an appropriate basis for a case of optimization of a range in a hypothetical invention having a very specific lumen size, but it does not support an optimization of ranges argument in the case of the presently claimed invention. The Examiner has located references that address individual parameters of the claimed invention, but has not provided any suggestion or motivation to combine these references except for the Applicants' own disclosure.

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For the sake of argument, even if the proposed combination were proper, Applicants submit that the relationship of the claimed invention is a critical relationship that is essential to the operation of the claimed catheter. Applicants point to M.P.E.P. 2144.05 II A in which an optimized range is unpatentable unless the range is shown to be critical. Applicants submit that this range is critical because if a catheter was constructed with an aggregate area of exit holes that is significantly larger than the cross-sectional area of a lumen then the catheter would not be able to deliver uniform fluid flow throughout the length of the infusion section of the catheter. That is, in such a catheter, fluid flow would primarily occur through the proximal-most exit hole, as discussed at length in the present application. Because the relationship has been shown to be critical to a main function of the claimed invention, it weighs in favor of patentability, even if the proposed combination were proper.

Lastly, in regard to the optimization argument, Applicants submit that in none of the references is it suggested that the relationship of the two dimensions is a *result-effective variable*. Indeed, none of the references even discuss the relationship between the combined area of the exit holes and the cross-sectional area of the lumen. Furthermore, there is no suggestion in any of the references that ties the altering of the individual parameters with the claimed relationship between those parameters, which advantageously result in uniformity of fluid flow from the exit holes. Therefore, the Applicants respectfully submit that routine experimentation would not result in the claimed invention because the Examiner has made no showing that the relationship between the combined exit hole area and the lumen cross-sectional area is a *result-effective variable*.

Claims 1 and 5 Have Been Amended

Although the notation made by the Examiner regarding the requirement of all the openings in the entire catheter to be less than the cross-sectional area of the lumen does not appear to be directly linked to the grounds of rejection, Applicants respectfully appreciate the clarifying nature of the suggestion. Applicants have elected to amend Claim 1 and 5 in the manner suggested by the Examiner to further distinguish the invention.

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Claims 2-3, 6-8, 11, and 12 are allowable because they depend from one of allowable Claims 1 and 5. These claims are also allowable on their own merit as well. Reconsideration and allowance of Claims 2-4 is respectfully requested.

CONCLUSION

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present claims. Accordingly, early issuance of a Notice of Allowance is most earnestly solicited.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the Claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney, Curtiss C. Dosier at (949) 721-7613 (direct line), to resolve such issue promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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